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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,715	01/14/2002	Yoshinobu Kiso	46/225	8223

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WASHINGTON, DC 20036-3307

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/14/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,715

Applicant(s)

KISO ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted January 30, 2003 is acknowledged. Note newly added claims 9 and 10 have been renumbered as 8 and 9. (See 37 CFR 1.126)

Claim Rejections 35 U.S.C.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alleviating sleep disorder, does not reasonably provide enablement for "preventing" sleep disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The state of the prior art indicates that sleep disorder associated with circadian dysrhythm may be caused by various reasons, including the usually reflect of jet lag. See Merck Manual, Fifteenth edition, at page 1375-1377. While there are many way to alleviating sleep disorder, no known method is available for preventing such disorders. There is no indication or suggestion that such disorder may be prevented from happening. Applicants fail to provide information allowing skilled artisan to ascertain that sleep disorder is in deed preventable. Applicants provide no working example, guidance or direction as how to employ the instant method for preventing sleep disorder. In absent of all these information, skilled artisan would not be able to practice the invention without undue experimentation.

Claim Rejection 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 6,7 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (EP 0,770,385, IDS MR).
3. Asami et al. teaches an anti-stress composition comprising astaxanthin and the method of using the same for treating stress. See the abstract and the claims, page 5, lines 41-55. Asami et

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al. further discloses that it is known in the art that stress cause somatic disorder as well as neurosis and depression. Stress destroys the ability of maintain homeostasis by the body. Conventional treatment of stress includes anti-anxiety agents and sleeping pills. See page 2, lines 9-14. Note, by definition, stress is reactions of the body to forces of a deleterious nature, infections, and various abnormal states that tend to disturb its normal physiologic equilibrium (homeostasis). (see Stedman's Medical dictionary). Normal circadian rhythm is part of homeostasis, and disturbance of circadian rhythm is a type of stress.

4. Asami et al. does not teach expressly to employ the astaxanthin containing composition for treating patient having disturbance of circadian rhythm.

5. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the astaxanthin containing composition for treating patient having disturbance of circadian rhythm because disturbance of circadian rhythm is a well-known type of stress. One of ordinary skill in the art would have reasonably expected that the astaxanthin-containing composition to be beneficial for patient having disturbance of circadian rhythm because the composition is known for anti-stressing. Furthermore, a composition useful for treating stress would have been reasonably expected to be useful for alleviating symptoms caused by stress, such as reduced homeostasis, or sleep disorder. As to claim 9, the recitation "suppressing degradation of in vivo melatonin" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See

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In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

6. Claim 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (EP 0,770,385, IDS MR) in view of Pierpaoli et al. (WO 88/07367).

7. Asami et al. teaches an anti-stress composition comprising astaxanthin and the method of using the same for treating stress. See the abstract and the claims, page 5, lines 41-55. Asami et al. further discloses that it is known in the art that stress cause somatic disorder as well as neurosis and depression. Stress destroys the ability of maintain homeostasis by the body. Conventional treatment of stress includes anti-anxiety agents and sleeping pills. See page 2, lines 9-14. Note, by definition, stress is reactions of the body to forces of a deleterious nature, infections, and various abnormal states that tend to disturb its normal physiologic equilibrium (homeostasis). (see Stedman's Medical dictionary). Normal circadian rhythm is part of homeostasis, and disturbance of circadian rhythm is a type of stress.

8. Asami et al. does not teach expressly the composition also comprising melatonin, or the employment of such composition for treating patient with disturbance of circadian rhythm.

9. However, Pierpaoli teaches that melatonin or its derivatives are known to be useful for treating patients having stress or acute anxiety as well as for the enhancement of immune resistance.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising both melatonin and astaxanthin for treating patients having stress or the symptoms caused by stress,

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including disturbance of circadian rhythm and symptoms caused by the disturbance of circadian rhythm.

A person of ordinary skill in the art would have been motivated to make a composition comprising both melatonin and astaxanthin for treating patients having stress or the symptoms caused by stress including disturbance of circadian rhythm and symptoms caused by the disturbance of circadian rhythm because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two anti-stress agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, disturbance of circadian rhythm, or sleep disorder is a well-known type of stress, e.g., it is known to treat stress with sleep pill.

Response to the Arguments

Applicants' amendments and remarks submitted January 30, 2003 have been fully considered, but are not persuasive for reasons discussed below.

The examiner does not state or suggest that stress is the only cause of disturbance of circadian rhythm, as indicated in the rejection, the examiner considers that the claimed invention read on disturbance of circadian rhythm caused by stress.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treated subject is stress free, or different type of activities) are not recited in the rejected claim(s). Although the

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claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, in view of the definition of stress (Stedman's Medical dictionary), the examiner has difficulty in imaging a patient having disturbance of circadian rhythm is free of stress.

11. Applicants argue that the combination of astaxanthin and melatonin unexpectedly provides synergistic effect. Regarding the establishment of unexpected results, a few notable principles are well settled. The evidence for supporting unexpected result must be clear and convincing. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, evidence the claimed subject matter must be compared with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e). The evidence as presented is neither clear nor convincing. Particularly, applicants provide no explanation as to why the data shown in Fig 5 is synergistic, not just an adduct. Further, examples 1 and 2 are confusing with respect of showing the significance of normalizing circadian rhythm. Both experiments show decrease of daylight activity and increase of dark-time activity. There is no disclosed correlation between the change of activities and normalization of circadian rhythm, or sleep disorder. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

12. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner


SHENGJUN WANG
PATENT EXAMINER
Shengjun Wang

4/9/03